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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,627	03/06/2002	Dan Yang	609920-600-025	1956

7590

03/19/2003

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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1676

DATE MAILED: 03/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/091,627

Applicant(s)

YANG ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other:  |

**First Office Action on the Merits**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of the instant claims create confusion because (a) the recitation of various definitions for similar R groups and "n", for example, R, in claim 1, has more than one definition; (b) period(s) in the middle of the claims (see for example, claims 1, 27 and 35) and (c) "m" is not define by the instant claims (see for example, claims 13 and 33). Thus, the ordinary artisan in the art would be unable to determine the metes and bound of the claimed invention.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bovicelli et al., Cicala et al., Holland et al. and Yang et al. (J. Org. Chem., 1998 or US Patent No. 5,763,623) in combination.

The claimed invention is a process for the production of predominantly 5,6-epoxides from the corresponding 5-ene steroid derivative in the presence of a ketone and an oxidant or the intermediate product thereof, i.e. a dioxirane.

Bovicelli et al. teach the epoxidation of various unsaturated steroidal compounds, including 3 $\beta$ -hydroxy-5,16-pregnadien-20-one acetate, utilizing dioxiranes produced in situ or in isolated form (see the entire article, especially page 2182, Scheme I, compound 4; page 2183, col. 1, 2<sup>nd</sup> paragraph). The reference teaches the production of a 3:2 ratio mixture of  $\beta$ - and  $\alpha$ -epoxides (see especially page 2184, col. 2, 1<sup>st</sup> paragraph).

Cicala et al. teach the epoxidation of various olefinic compounds, including 4 $\beta$ -hydroxycholestreol, utilizing dioxiranes generated in the reaction of potassium caroate with acetone (see the entire article, especially col. 2671, compound 4; col. 1, 1<sup>st</sup> paragraph).

Holland et al. teach the epoxidation of epicholesterol and the production of a mixture comprising 3 $\alpha$ -hydroxy-5 $\beta$ ,6 $\beta$ -epoxycholestane (see the entire article, especially page 3135, Scheme I).

Yang et al. (J. Org. Chem. 1998) teach various ketone catalysts useful in the epoxidation of olefins with oxone (see the entire article, especially Abstract; page 8953, col. 1, Chart 1; page 8954, Tables 1 and 2).

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Yang et al. ('623) teach the use of various ketones in the catalytic epoxidation of olefinic compounds (see the entire article, especially col. 1, lines 8-65). The reference teaches (a) the epoxidation of any olefin (see col. 1, lines 29-34; 59-64; col. 10, lines 5-20) and (b) the use of solvent systems such as acetonitrile-water and tetrahydrofuran-water; buffers such as sodium bicarbonate; oxidants such as oxone and potassium peroxomonosulfate; temperature ranging from 0° to 40°C and pH ranging from 7 to 8 (see col. 4, lines 10-23; col. 10, lines 15-20).

Based on the combined teachings of the above-cited references and the level of skill of the ordinary artisan in the art at the time of the invention, the utilization of a dioxirane derivative, produced in situ or in isolated form, in the epoxidation of olefinic compounds would have been obvious. The skilled artisan in the art at the time of the invention would have the reasonable expectation that (a) any 5-ene steroid derivative, including 3 $\alpha$ -substituted-5-ene isomers, would undergo epoxidation with the production of the corresponding 5,6-epoxy compound(s) (see Bovicelli et al., Cicala et al. and Holland et al.) and (b) dioxirane derivatives are produced in situ by the reaction of a ketone and an oxidant such as peroxomonosulfate (see especially Cicala et al., pages 2670, 1<sup>st</sup> paragraph – page 2671, 1<sup>st</sup> paragraph; Yang et al., J. Org. Chem., page 8952, Introduction). The motivation to utilize various ketones and/or dioxirane derivatives would be based on the desire to obtain catalyst(s) having optimum epoxidation properties.

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***Other Matters***


5. The data presented in the present specification is noted. However, the data therein does not commensurate in scope with the claimed invention. In addition, as indicated above, the reaction condition would be expected by the ordinary artisan to influence the yield and the isomeric form of the end product and it is within the level of skill of said artisan to find the optimum condition that would lead to the production of predominantly 5 $\beta$ ,6 $\beta$ -epoxy steroid derivatives.

***Telephone Inquiry***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB  
March 17, 2003